Sheryl P. Walter Declassified/Released US Department of State EO Systematic Review 20 Mar 2014

Message Text

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PAGE 01 STATE 139960
ORIGIN HEW-06

INFO OCT-01 EUR-12 NEA-11 ISO-00 OES-07 /037 R

DRAFTED BY DHEW/FDA: JRWEINROTH, MD:VO
APPROVED BY OES/ENP/EN: BLONG
DHEW/PHS/OASH/OIH: REVANS
NEA/IRN:MGREENE(INFO)
EUR/NE:WNEWLIN(INFO)
----------054749 021904Z /72
P 021838Z JUN 78
FM SECSTATE WASHDC
TO AMEMBASSY TEHRAN PRIORITY
AMEMBASSY BRUSSELS PRIORITY

UNCLAS STATE 139960

E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, TBIO, IR, BE

SUBJECT: FDA ADVISORY - DIAGNOSTIC X-RAY MACHINE NOT IN COMPLIANCE WITH FDA PERFORMANCE STANDARD (RECALL R-033-6)

1. FDA ADVISES OF THE FOLLOWING:
PRODUCT INVOLVED - DIAGNOSTIC X-RAY MACHINE INCORPORATING AN IMAGE INTENSIFIER COMPONENT USED IN TOMOGRAPHIC AND FLUOROSCOPIC WORK.

2. PRODUCT IDENTIFICATION - THE PRODUCTS ARE THE TELEGEM 90 TABLE SYSTEM MANUFACTURED BETWEEN AUGUST 1, 1974 AND APRIL 14, 1976, AND THE FLUORICON-300 IV IMAGE INTENSIFIER (COMPONENT) MANUFACTURED BETWEEN AUGUST 1, 1974 AND MAY 20, 1976.

3. MANUFACTURER/RECALLING FIRM - THE RECALLING FIRM IS THE MANUFACTURER GENERAL ELECTRIC COMPANY, MEDICAL SYSTEMS
UNCLASSIFIED

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PAGE 02 STATE 139960

DIVISION, P.O. BOX 414, MILWAUKEE, WISCONSIN 53201.

4. REASON FOR RECALL - THE TELEGEM-90 X-RAY MACHINES HAVE BEEN DETERMINED TO BE IN NONCOMPLIANCE WITH THE FOLLOWING SECTIONS OF THE REGULATIONS ISSUED PURSUANT TO THE RADIATION CONTROL FOR HEALTH AND SAFETY ACT OF 1968.

Sheryl P. Walter Declassified/Released US Department of State EO Systematic Review 20 Mar 2014

Sheryl P. Walter Declassified/Released US Department of State EO Systematic Review 20 Mar 2014

21 CFR 1020.30 (H) (3) (VI): A STATEMENT OF THE ACCURACY
OF THE TOMOGRAPHIC EXPOSURE TIMES IS NOT PROVIDED TO THE
USER.

21 CFR 1020.31 (A) (1): THERE IS NO PREINDICATION OF
THE TOMOGRAPHIC EXPOSURE TIMES.

21 CFR 1020.32 (D) (1): THE "RECORD TEST" EXPOSURE
SWITCH ALLOWS FLUOROSCOPIC EXPOSURE RATES IN EXCESS OF
10 ROENTGENS PER MINUTE AS ALLOWED BY THE STANDARD.

THE FLUORICON-300 IMMAGE INTENSIFIERS ARE IN NONCOMPLIANCE
WITH 21 CFR 1020.32 (D)(1): THE "RECORD TEST" EXPOSURE
SWITCH ALLOWS FLUOROSCOPIC RATES IN EXCESS OF STANDARD.
THE PLAN OF MODIFICATION CONSISTS OF NOTIFYING AFFECTED
PERSONS BY CERTIFIED MAIL AND PROVIDING EACH USER WITH
THE NECESSARY USER INFORMATION AND PERFORMING ALL
MODIFICATIONS AT NO COST TO THE USER. THE CORRECTIVE
ACTION PROGRAM TO BRING THE SUBJECT UNITS INTO COMPLIANCE
CONSISTS OF THE FOLLOWING:

TOMOGRAPHIC EXPOSURE TIME WILL BE INDICATED ON THE
CONTROL OF THE TELEGEM-90 TABLE SYSTEM.

TOMOGRAPHIC EXPOSURE TIME ACCURACY WILL BE INCLUDED IN
THE OPERATING MANUAL FOR THE TELEGEM-90 TABLE SYSTEM.
UNCLASSIFIED

THE "RECORD TEST" FUNCTION WILL BE DISABLED ON ALL
MACHINES WHICH UTILIZE THE FLUORICON-300 IV IMAGE
INTENSIFIER.

FIELD MODIFICATION INSTRUCTIONS WILL BE SENT TO ALL GE
DISTRICT SERVICE MANAGERS. THESE MANAGERS WILL PERFORM
ALL NECESSARY MODIFICATIONS.

EACH CUSTOMER WILL SIGN A CERTIFICATION FORM TO BE
RETURNED TO GE, VERIFYING THAT THE CORRECTIONS WERE
PERFORMED.

5. THE GE PERSON TO BE CONTACTED REGARDING THIS RECALL IS:
MR. JOHN E. OLSSON
PRODUCT ASSURANCE ENGINEERING
GENERAL ELECTRIC COMPANY
MEDICAL SYSTEMS DIVISION
P.O. BOX 414
MILWAUKEE, WISCONSIN 53201
TELEPHONE: 414-383-3211

Sheryl P. Walter Declassified/Released US Department of State EO Systematic Review 20 Mar 2014

Sheryl P. Walter Declassified/Released US Department of State EO Systematic Review 20 Mar 2014

6. POSTS ARE REQUESTED TO CONTACT FOREIGN PURCHASERS TO DETERMINE IF THEY HAVE BEEN ADVISED OF CORRECTIVE ACTIONS REQUIRED FOR DEVICE TO MEET PERFORMANCE STANDARDS. ANY QUESTIONS WITH RESPECT TO THIS ADVISORY SHOULD BE REFERRED TO G.E.

7. FOREIGN PURCHASERS:

SAZEMAN SHAHAMSMAMI
KHADONATE EJTEMAIE
GHAVAMOL SALTANEH STREET
TEHERAN, IRAN
FDO NO. 63596
C7005F CATALOG NO. FOR MODEL NO. 46-16416492 BASIC
UNCLASSIFIED

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PAGE 04 STATE 139960

IMAGE INTENSIFIER CONTROL CABINET (FLOURION 300)

G.E. MEDICAL
RUE MARIE CURIE
LANCIN, LIEGE, BELGIUM
ULTIMATE DESTINATION ITALY
SERIAL NO. 312 351
FDO NO. 51734
C7005F BASIC IMAGE INTENSIFIER
CONTROL CABINET CHRISTOPHER

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NNN

Sheryl P. Walter Declassified/Released US Department of State EO Systematic Review 20 Mar 2014

Message Attributes

Automatic Decaptioning: X
Capture Date: 01 jan 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: RECALL, EQUIPMENT, MEDICAL CARE
Control Number: n/a
Copy: SINGLE
Draft Date: 02 jun 1978
Decaption Date: 01 jan 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 jan 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1978STATE139960
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, MD:VO
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D780231-0851
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1978/newtext/t197806101/aaaadiya.tel
Line Count: 146
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: e10d777c-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 3
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 29 mar 2005
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: N/A
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 2140118
Secure: OPEN
Status: NATIVE
Subject: FDA ADVISORY - DIAGNOSTIC X-RAY MACHINE NOT IN COMPLIANCE WITH FDA PERFORMANCE STANDARD (RECALL R-033-6)
TAGS: OGEN, ETRD, EIND, TBIO, IR, BE
To: TEHRAN BRUSSELS
Type: TE
vdkvgwkey: odbc://SAS/SAS.dbo.SAS_Docs/e10d777c-c288-dd11-92da-001cc4696bcc
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Sheryl P. Walter
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EO Systematic Review
20 Mar 2014
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